JAMES M. BRUGGER et al. Application No.: 09/595,167 Page 6

# <u>REMARKS</u>

Claims 1-3, 5-7, 10, 12, 14, and 16-27 have been examined. Claims 1 and 17 have been amended. Claim 4 has been canceled. Dependent claims 8, 11, and 13 stand withdrawn as being drawn to a non-elected species. Currently, claim 1 is generic. Re-examination and reconsideration of the pending claims 1-3, 5-8, 10-14, and 16-27, as amended, are respectfully requested.

### Rejections Under 35 U.S.C. § 102

Claims 1-3, 5, 7, 10, 12, 14, 16-21, 23, and 27 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,681,560 issued to Schulte et al. Such a rejection is traversed in part and overcome in part as follows.

In order to expedite prosecution of this case and to more clearly claim the present invention, Applicants have now amended independent claim 1 to recite an implantable port comprising a port body having a flow passage therethrough and a pressure-responsive valve. The flow passage has an upstream end and a downstream end, wherein at least a portion of the upstream end is adapted to sealingly engage an access tube which is inserted into said upstream end. In particular, the pressure-responsive valve element is positioned in the flow passage and <u>integrally formed with the port body</u> downstream from the upstream portion so that an access tube can be fully inserted into said upstream portion so that an access tube can be fully inserted into said upstream portion so that an access tube can be fully inserted into said upstream portion so that an access tube can be fully inserted into said upstream portion so that an access tube can be fully inserted into said upstream portion so that an access tube can be fully inserted into said upstream portion without engaging the valve component, wherein the valve component is closed in the absence of a differential pressure above a threshold level. Such an integral pressure-responsive valve element within the port body has not been reasonably disclosed or suggested by the cited art.

As the Examiner certainly knows and appreciates, the cited reference must teach each and every element of the claim to establish anticipation under 35 U.S.C. § 102. M.P.E.P. § 2131. The Court of Appeals for the Federal Circuit has held that, "the identical invention must be shown in as complete detail as is contained in the .... claims." *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1912, 1920 (Fed. Cir. 1989). The Schulte

PATENT

Ø012

JAMES M. BRUGGER et al. Application No.: 09/595,167 Page 7

et al. reference is clearly distinguishable from claim 1. With reference to Figs. 1 and 7, Schulte et al. describes an injection site apparatus (28) having an outlet (58). A <u>separate</u> <u>flexible tubing structure 26</u> is connected to the injection site apparatus (28) via outlet (58) and a reservoir (12). In particular, the flexible tubing <u>has an inlet end 56 which includes</u> <u>a one way valve (60)</u> situated therein (26) to prevent reverse flow of medication from the reservoir (12). See col. 7, lines 25-32. This reference fails to teach or suggest a valve as an element of the port, much less as integrally formed within the port.

The presently claimed invention of claim 1, in contrast, now sets forth that the valve element (40) is positioned in the flow passage (20) and integrally formed within the port body (11). Support for this limitation is found in Fig. 1 and accompanying text on page 5, lines 1-9. Hence, absent any cited teaching or suggestion for an implantable port comprising a pressure-responsive valve element integrally formed with the port body as now recited in claim 1, claim 1 (and dependent claims 2, 3, 5-8, 10-14, 16 and 27) are now in condition for allowance.

Amended independent claim 17 recites a method for delivering a substance to a subcutaneous target site. The method similarly comprises, in part, percutaneously introducing an access tube to an implanted port having a flow passageway with an upstream end, a downstream end, and <u>a valve element</u> in the flow passageway and <u>integrally formed with the port</u>, wherein the access tube is introduced to seat in the passage but does not engage the valve element. Hence, claim 17 (and dependent claims 18-23) are allowable for many of the reasons given above regarding claim 1.

#### Rejections Under 35 U.S.C. § 103

Claims 24-26 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Schulte et al. in view of U.S. Patent No. 6,162,238 issued to Kaplan et al. Such a rejection is traversed.

With respect to independent claim 24, Applicants respectfully note that the Kaplan et al. reference has an effective filing date of February 24, 1999, <u>not</u> the January 18, 1994 date as cited by the Examiner on page 4 of the Office Action. Applicants fail to

### PATENT

Ø013

PATENT

JAMES M. BRUGGER et al. Application No.: 09/595,167 Page 8

see any earlier effective filing date, in particular the January 18, 1994 date, or any related U.S. Application Data on the Kaplan et al. patent. The present application is a continuation-in-part of and claims priority from Application No. 09/239,411 filed on January 28, 1999. Applicants believe that claims 24-26 are fully supported under 35 U.S.C. § 112 in the '411 parent application. Hence, the present application has an effective filing date of January 28, 1999, not the June 15, 2000 date as noted by the Examiner on page 4 of the Office Action. Under M.P.E.P. § 706.02, the Kaplan et al. reference does not appear to be prior art to the present application, and as such, Applicants respectfully request that the § 103(a) rejection be withdrawn and claim 24 (and dependent claims 25 and 26) be allowed.

JAMES M. BRUGGER et al. Application No.: 09/595,167 Page 9

PATENT

# <u>CONCLUSION</u>

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is urged. If the Examiner believes a telephone conference would aid in the prosecution of this case in any way, please call the undersigned at 415-273-8317.

Respectfully submitted,

Nena Bains

Reg. No. 47,400

TOWNSEND and TOWNSEND and CREW LLP Two Embarcadero Center, 8<sup>th</sup> Floor San Francisco, California 94111-3834 Tel: 650-326-2400 Fax: 415-576-0300 NB: SF 1451552 v1